

### **REMARKS**

Upon entry of the amendments, claims 1 and 3-55 will be pending. Applicant gratefully acknowledges that the Examiner has allowed claims 1, 4-9, 11-14, and 17-24.

Claims 1, 3, 10, 14-16, 25, and 43 have been amended to more clearly define the subject matter regarded as the invention. The amendments are fully supported by the specification and originally filed claims and, therefore, do not add new matter.

It is submitted that the amendments do not require a new search or consideration because the amendments merely clarify the claimed subject matter and do not change the subject matter under consideration. The amendments do not add more claims than were finally rejected and, it is submitted, place the claims in condition for allowance, or in better condition for appeal. As such, it is respectfully requested that the amendments be entered.

### **Rejections Under 35 U.S.C. § 112**

Claims 3, 10, 15, 16, and 25-55 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. The rejection is traversed for the reasons set forth below.

With regard to claims 3 and 43, it is alleged that the claims are indefinite because the phrase “test cells that do not survive subjection to the environmental conditions as having the transposon in an essential chromosomal gene” is unclear. Applicant initially points out that claim 3 has been amended to clarify that identifying one or more of the haploid test cells that contain transposon-mutagenized DNA in an essential chromosomal gene therein comprises selection of test cells that do not survive subjection to the environmental condition.

In particular, the Examiner alleges that Table 1 in the specification illustrates that cells with the transposon in the essential chromosomal gene from the test organism will survive subjection to an environmental condition and, therefore, it is unclear how to use

lack of survival to identify an essential gene when the disrupted essential chromosomal gene is from the test organism. Applicant submits, however, that one skilled in the art would understand the metes and bounds of the subject matter of claims 3 and 43 because the specification clearly describes using lack of survival for identification of an essential gene. For example, the specification discloses that insertion of a transposon into an essential gene may be lethal and prevent a cell from surviving, or insertion of a transposon into an essential gene may allow survival of the cell, but result in severely diminished growth or metabolic rate. Alternatively, insertion of a transposon into an essential gene may be conditionally essential such that its function is required for cell viability and growth under certain conditions, but not under other conditions (see, for example, paragraph 0053).

With respect to the illustrative examples set forth in the specification in Table 1 of Example 1, Applicant points out that survival of cells is dependent on both the location of the transposon and the subjection to an environmental conditions. In particular, the six different clones exemplified in Table 1 are differentiated by survival in the absence or presence of drugs (e.g., Chloramphenicol (Cm) and Kanamycin (Km)) and by temperature changes (e.g., 30°C to 43°C). As such, Table 1 sets forth, for each of the six exemplified clones, environmental conditions in which test cells either do not survive or that selectively prevent replication, including disruption of an essential chromosomal gene from the test organism (e.g., Table 1, clone F). Furthermore, additional methods for using lack of survival to identify an essential gene are disclosed in Example 2 (see, for example, paragraphs 0064-0067).

For the reasons set forth above, Applicant respectfully submits that one skilled in the art would understand the metes and bounds of the subject matter of claims 3 and 43. As such, removal of this ground of the rejection is respectfully requested.

With regard to claim 10, it is alleged that metes and bounds of the term “selectively” are unclear because it is unknown what the term pertains to. In order to address potential ambiguity, the term “selectively” has been deleted from claim 10 in

accordance with the Examiner's suggestion, thereby rendering the rejection moot. As such, removal of this ground of the rejection is respectfully requested.

With regard to claims 15 and 16, it is alleged that the metes and bounds of the phrase "identified essential chromosomal gene has 80% (90%) sequence identity" are unclear because the identified gene and the known segment of DNA are one and the same piece of DNA and it is therefore unclear how the essential gene can have less than 100% identity to itself. To clarify the subject matter regarded as the invention claims 14-16 have been amended to refer to a gene in the known segment of DNA from the "haploid host cell". As such, Applicant submits that the currently amended claims 14-16 render the rejection moot and request withdrawal of this ground of the rejection.

With regard to claim 25, it is alleged that the metes and bounds of the claim term "suitable culture medium" are unclear because the term "suitable" is relative and no single set of conditions is recognized in the art or set forth in the specification. Applicant respectfully traverses for reasons previously made of record and submits that one skilled in the art would understand that the term "suitable" is not a relative term, but is determined by selection of the host cell being cultured. Applicant further submits that based on the knowledge in the art regarding medium suitable for culturing haploid cells, the skilled artisan would clearly understand the metes and bounds of the claim with respect to a suitable culture medium. In order to advance prosecution, however, claim 25 has been amended to more clearly set forth that the culturing one or more of the merodiploid test cells involves a culture medium suitable for viability of a wild-type haploid test cell while further introducing the environmental condition. Accordingly, withdrawal of this round of the rejection is respectfully requested.

Further with regard to claim 25, it is alleged that the claims are indefinite because the phrase "test cells that do not survive subjection to the environmental conditions as having the transposon in an essential chromosomal gene" is unclear. In particular, the

Examiner alleges that Table 1 in the specification illustrates that cells with the transposon in the essential chromosomal gene from the test organism will survive subjection to an environmental condition and, therefore, it is unclear how to use lack of survival to identify an essential gene when the disrupted essential chromosomal gene is from the test organism.

Applicant initially submits that final rejection is premature because this new ground of rejection was not necessitated by a previous amendment by the Applicant. Final rejection on a second of subsequent action on the merits is improper where the Examiner introduces a new ground of rejection that is neither necessitated by Applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) (see MPEP 706.07(a)). Here, the Examiner has, for the first time, rejected the claims based on an alleged lack of clarity with respect to the cited claim terminology. Applicant points out, however, that the terminology of claim 25 cited by the Examiner was present in the claim 25 as originally filed and has not been subject to amendment. As such, Applicants submit that previous amendments to claim 25 did not necessitate the Examiner's current rejection, and that the rejection could have been made at any previous point in the prosecution. Accordingly, it is submitted that final rejection is premature and Applicants respectfully request withdrawal of final rejection.

Regardless of whether final rejection is appropriate, Applicant further submits, as set forth above, that the specification clearly describes using lack of survival for identification of an essential gene and the metes and bounds of claim 25, therefore, would be apparent to one skilled in the art viewing the specification (see, for example, paragraph 0053; Example 1; Example 2). Furthermore, with respect to Table 1 of Example 1, Applicants point out the exemplified clones do not necessarily survive any environmental condition, rather the survival of cells is dependent on both the location of the transposon and the subjection to an environmental conditions. As such, Applicant respectfully submits that the skilled artisan would understand the scope of subject matter

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of claim 25 and respectfully request reconsideration and withdrawal of the rejection of claim 25.

For the reasons set forth above, Applicant submits that the current claims meet all requirements under 35 U.S.C. § 112, second paragraph, and respectfully request reconsideration and withdrawal of the rejection of claims 3, 10, 15, 16, and 25-55.

In view of the amendments and the above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicant's representative if there are any questions relating to this application.

Please charge any additional fees, or make any credits, to Deposit Account No. 07-1896.

Respectfully submitted,



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